UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re: BAIR HUGGER FORCED AIR WARMING PRODUCTS LIABILITY LITIGATION	MDL No. 15-2666 (JNE/FLN)
This Document Relates To: *All Cases*	

PLAINTIFFS' RESPONSE OPPOSING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

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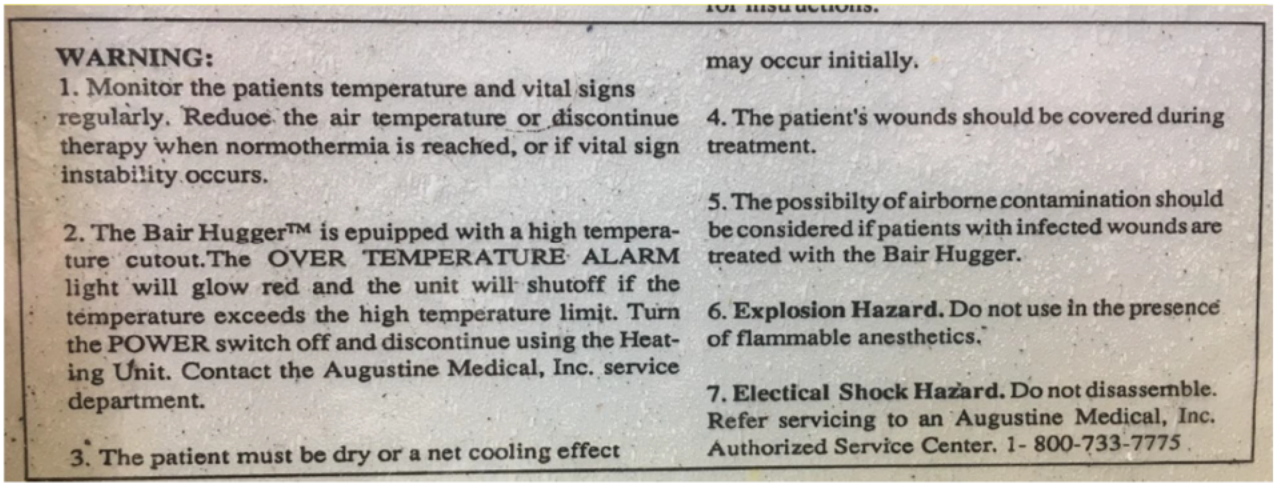
I. INTRODUCTION

With a straight face, Defendants move this Court for an order granting summary judgment in their favor, asserting at this "general causation" stage in these proceedings that there is no genuine issue of material fact as to whether or not the Bair Hugger is capable of causing periprosthetic joint infections as Plaintiffs allege in their Master Long Form Complaint. Defendants' bring their motion despite knowledge about the risk of infection as a result of airborne contamination dating back to the 1980s with the Bair Hugger 200 series:[1]



WARNING:
1. Monitor the patients temperature and vital signs regularly. Reduce the air temperature or discontinue therapy when normothermia is reached, or if vital sign instability occurs.

2. The Bair Hugger™ is epuipped with a high temperature cutout.The OVER TEMPERATURE ALARM light will glow red and the unit will shutoff if the temperature exceeds the high temperature limit. Turn the POWER switch off and discontinue using the Heating Unit. Contact the Augustine Medical, Inc. service department.

3. The patient must be dry or a net cooling effect may occur initially.

4. The patient's wounds should be covered during treatment.

5. The possibilty of airborne contamination should be considered if patients with infected wounds are treated with the Bair Hugger.

6. **Explosion Hazard.** Do not use in the presence of flammable anesthetics.

7. **Electical Shock Hazard.** Do not disassemble. Refer servicing to an Augustine Medical, Inc. Authorized Service Center. 1- 800-733-7775

Defendants deny that a triable issue of fact exists, yet their own internal documents recognize a reasonable alternative design avoids the following known risks associated with use of Bair Hugger forced air warming intra-operatively:[2]

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[1] Ex. 1, Photo of warning label in Bair Hugger Model 200. All references to Ex. __ are references to exhibits to the Declaration of Genevieve M. Zimmerman in Support of Plaintiffs' Response Opposing Defendants' Motion for Summary Judgment, filed concurrently herewith.

[2] Excerpt from Ex, 2 (3MBH00982867-85).

Internal notations on company ñtalking points for salesò are even more plain:[3]

Yet throughout the course of this litigation, Defendants have mocked Plaintiffsô allegations of a causal relationship between the Bair Hugger and infection. For purposes

[3] Ex. 3 (3MBH00001389).

of this motion for summary judgment, any doubt as to genuine issues of material fact must be resolved in favor of the non-moving party: the Plaintiffs.

3Môs motion for summary judgment does nothing more than parrot the same arguments it makes in its *Daubert* motions ï and again, those arguments are without merit. Indeed, 3M concedes that ñso long as the Court excludes Plaintiffsô three medical experts ï Dr. Samet, Dr. Jarvis, and Dr. Stonington ï summary judgment is appropriate.ò Logic therefore dictates that if the Court does not completely exclude Dr. Samet, Dr. Jarvis, or Dr. Stonnington, the Court must deny Defendantsô motion. For the reasons explained herein and in response to 3Môs *Daubert* motions, the motion for summary judgment should be denied. To conclude otherwise would be clear reversible error. *See, e.g.*, *Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 564 (8th Cir. 2014) (reversing exclusion of plaintiffôs experts).

Plaintiffsô experts have reliably and properly ñruled-inò the Bair Hugger system as a cause of deep joint infections. As a respected epidemiologist, for example, Dr. Samet followed well-accepted methods in drawing causal inferences based on the totality of evidenceð ranging from the peer-reviewed epidemiological study conducted by McGovern et al. to a plethora of published studies showing how the Bair Hugger increases the amount of particles and thus bacteria at the surgical site. Drs. Jarvis and Stonington reached the same conclusion based on different yet equally availing methods, while Dr. Elghobashi demonstrated the mechanism by which Bair Hugger increases the risk of deep joint infection in orthopedic patients.

Moreover, as explained below and in Plaintiffsô responses opposing 3Môs *Daubert* motions[4], the Eighth Circuitôs decision in *Glastetter* does not stand for the proposition that an expert cannot find causation based on studies that expressly disclaim the same. Textbook epidemiology teaches that scientists may rely associations reported from statistical studies along with the full gamut of evidence in drawing causal conclusions. So even if the individual studies cited by Plaintiffsô experts do not explicitly find causation, neither that fact nor the contrary views of ECRI or any other organization *ipso facto* precludes Plaintiffsô experts from finding causation. To hold otherwise would improperly elevate Plaintiffsô burden of proof. For that reason, no case in this Circuit has adopted a ñconclusive studyò rule, and 3M tellingly fails to cite one.

3M also contends that Plaintiffsô medical experts and those experts alone can opine on general causation. But none of the cases that 3M citesð including *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1210 (8th Cir. 2000), or *Barrett v. Rhodia, Inc.*, 606 F.3d 975, 982-93 (8th Cir. 2010), discussed *infra* at 18ð come even close to establishing that radical proposition. For these reasons and others discussed herein, 3M falls well short of its burden. The Court should deny Defendantsô motion.

[4] Doc. 758, Doc. 879, and 914.

II. RELEVANT FACTUAL BACKGROUND

A. Reliable Science Establishes Both the Foundation and the Mechanism by Which Bair Hugger Causes Deep Joint Infection

Periprosthetic Joint Infection (ñPJIò aka ñDJIò) is a well-known, often feared problem in the orthopedic community. PJI rates are going up,[5] while other surgical site infection rates are decreasing.[6] PJIs require multiple additional surgeries, including two-stage revision surgery, and even amputation or death in extreme cases.

PJIs are caused by bacteria. That much is undisputed. Bacteria that causes PJIs is introduced at time of surgery.[7] Clinical trials have long confirmed that between 80 and 90% of bacterial contaminants found in the wound come from colony-forming units (ñCFUsò) present in the air of the operating room.[8] As little as a CFU can cause a PJI.[9]

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[5] Ex. 4 Kurtz, Steven M., et. al., *Economic Burden of Periprosthetic Joint Infection in the United States*, J. OF ARTHROPLASTY, Vol. 27, No. 8 Supp. 1 (2012).

[6] *See* Agency of Healthcare Research and Quality: *National Scorecard on Rates of Hospital-Acquired Conditions 2010 to 2015: Interim Data from national Efforts to Make Health Care Safer* (available at https://www.ahrq.gov/professionals/quality-patient-safety/pfp/2015-interim.html#exhibit7)(last visited October 2, 2017).

[7] *See* Ex. 5, Wagner, Jennifer A., et. al. *Using Cleanroom Technology: Improving Operating Room Contamination Control*, ASHRAE (February 2014)(citing Howorth, F.H., *Prevention of Airborne Infection during Surgery*, LANCET (1985) 325:386-388)). The majority of periprosthetic joint infections are initiated through the introduction of microorganisms at the time of surgery. Ex. 6, Mont Dep. (319:10-14); The bacteria that causes the periprosthetic joint infection was obtained during the surgery. Ex. 7 Wenzel Dep. (185:17-186:2).

[8] *See* Ex. 5 (Wagner)(citation omitted).

[9] *See* Doc 315 # 1. *See also* Ex. 7, Wenzel Dep. (157:17-20)(The infectious dose for an implant is less when there is no implant.); Ex. 17, 30(b)(6) Dep. (304:18-23).

Bacteria is typically transmitted by attaching to particles.[10] An increase in 10 micron sized particles equates to an increased number of bacteria.[11] Skin Squames are the majority of particles in an operating room.[12] According to ASHRAE, between one million and 900 million squames fall during a surgery lasting between two and four hours.[13] The average size of a skin squame is 10 microns.[14] These particles can become ñaerosolizedò, or airborne.[15] Aerosolized bacteria is also known as airborne contamination.[16] Airborne contamination can affect the implant, the hands of the surgeon,

[10] Ex. 5 (Wagner)(citation omitted).
[11] Ex. 8, Stocks GW, Self SD, et.al. *Predicting bacterial populations based on airborne particulates: A study performed in nonlaminar flow operating rooms during joint arthroplasty surgery*, AMERICAN JOURNAL OF INFECTION CONTROL (2010) 38(3):199-204 (noting an increase in 10 micron particles directly correlates to increases CFUs). *See also* Ex. 7, Wenzel Dep.(309:19-310:3;322:18-21).
[12] *See* Ex. 5.
[13] *Id.*
[14] *See, e.g.*, Ex. 9, Memarzadeh and A. P. Manning, *Comparison of Operating Room Ventilation Systems in the Protection of the Surgical Site*, ASHRAE TRANS., vol. 108, pp. 4549ï 4552, 2002.
[15] *Id*.
[16] Ex. 10, *Operative Environment, International Consensus of Orthopedic Surgeons*, J ORTHOP RES 32:S60-S80 (2014).

and the surgical instruments.[17] Airborne contamination also, of course, can affect a patientôs surgical site.[18]

Where bacterial counts are increased, the risk of PJI is also increased. A recent article by Dairouche, et. al., confirmed that when the bacterial load is increased near the surgical site, there is a statistically significant increase in PJIs.[19] Defendantsô proffered infectious disease expert, Dr. Richard Wenzel, agrees with the Dairouche study,[20] and considers Dr. Darouiche an expert.[21] Dr. Wenzel agrees that there is a correlation with bacterial load in the air and PJIs.[22] The International Consensus of Orthopedic Surgeons (ñICOSò) also confirms the number of bacteria arriving at surgical wound correlate

[17] *See* Ex. 6, Dep. Mont (321:5-21)(Disruption of the unidirectional flow in an operating room can potentially cause the instruments, hands of the surgeon, and the implant to become contaminated.). *See also A Guide to Infection Control in the Hospital*. Editors: Wenzel RP, Edmond M, Pittet D, Devaster J-M, Geddes A, Butzler J-P. Hamilton, London: B.C. Decker Inc., 2004 4th edition (Exogenous contamination of wounds is also important in the pathophysiology of SSIs, particularly for clean surgical procedures. Airborne bacteria originating from the patient or the surgical team suffice to create SSI in these types of procedures, particularly when implants are being placed (e.g., total hip prostheses)).

[18] Ex. 10. Indeed, ECRI, often cited by Defendants, recently proclaimed that patient-warming devices ñshould have HEPA-grade or better air filters to reduce the risk that airborne dust, bacteria, and mold will be blown onto the patient or into wounds.ò *See* Ex. 32. Of course, the Bair Hugger does not meet this ECRI standard.

[19] Ex. 11, Darouiche, R., Green, D., Harrington, M., Ehni, B., Kougias, P., Bechara, C., & OôConnor, D., *Association of Airborne Microorganisms in the Operating Room With Implant Infections: A Randomized Controlled Trial*. INFECTION CONTROL & HOSPITAL EPIDEMIOLOGY, (2017). An increase CFUs does not, however, correlate with an increased rate of surgical site infection (ñSSIò). *Id.*

[20] Ex. 7, Wenzel Dep. (170:13-20).

[21] *Id.* at (78:14-18).

[22] *Id.* at (169:4-22;322:22-323:6).

directly with the probability of PJI.[23] Defendantsô orthopedic expert, Dr. Michael Mont, agrees the ICOS is ñextremely authoritativeò.[24]

Given the indisputable concern about bacteria in an operating room causing PJIs, experts measure levels of airborne contamination. Particle count has long served as a proxy for the amount of bacteria or ñbioburdenò in the air.[25] ICOS recognizes the use of particle counting to approximate bacterial levels in an OR.[26] Even Defendantsô retained consultant on microbiology long agreed ñparticles counts serve as a reasonable surrogate for bioburden of air in an OR.ò[27]

Orthopedic surgeons are concerned about particles because they are capable of transmitting pathogens, including bacteria.[28] Defendants knew orthopedic surgeons are and have long been concerned about particles.[29] Defendants knew from the International Consensus meeting on Prevention of Periprosthetic Joint Infection that ñthey equate

[23] Ex. 10 (ICOS Question 1).
[24] Ex. 6, Mont Dep. (303:3-25).
[25] See., e.g., Ex. 11; Ex. 8; Ex. 12, Raval, et al. *Real-time monitoring of non-viable airborne particles correlates with airborne colonies and represents an acceptable surrogate for daily assessment of cell-processing cleanroom performance*, CYTOTHERAPY, (2012); Ex. 13,Zheng, et al. *Concentrations and Size Distributions of Airborne Particulate Matter and Bacteria in an* Experimental Aviary Laying-Hen Chamber. *Journal of the American Society of Agricultural and Biological Engineers,* (2013); Ex. 14, Seal and Clark, *Electronic Particle Counting for Evaluating the Quality of Air in Operating-Theaters - a Potential Basis for Standards*, THE JOURNAL OF APPLIED BACTERIOLOGY, (1990).
[26] Ex. 10, (ICOS Question 2).
[27] See Ex. 15, 3MBH00050770 (email from Gary Hansen to Dr. Russell Olmstead, 3/1/2010)
[28] See, e.g., Ex. 10, (ICOS Question 1 & 2)
[29] Ex. 17, 30(b)(6) Dep. of Al Van Duren (301:2-10).

particulates with bacteria in the air.ò[30] Defendantsô infectious disease expert, Dr. Richard Wenzel, testified approximately 40% of particles carry bacteria.[31] Orthopedic surgeons are concerned if a device brings up bioburden from underneath the operating room table and puts it over the surgical site,[32] yet Defendantsô own expert confirmed particles under the operating table and/or on the floor of the operating room can be transported to the surgical site by use of the Bair Hugger.[33]

None of these indisputable facts and scientific principles outlined, *supra*, in Section A are connected in any way to Dr. Augustine, and cannot be cast aside as bad blood or vendetta. And despite knowing about the relationship between particles and bacteria, despite knowing these bacteria-laden particles can be aerosolized and transported through the air to the surgical site, and despite the admittedly understanding that orthopedic surgeons would be concerned about Bair Huggerôs role in connecting this chain, 3M intentionally and continually refuses to acknowledge the risk to patients, or to warn patients or healthcare providers about the known risk.

[30] Ex. 18, 3MBH00580475.
[31] Ex. 7, Wenzel Dep (50:2-15).
[32] Ex. 6, Mont Dep. (331:4-8;337:10-15);
[33] Ex. 19, Keuhn Dep. (324:5-12).

B. Bair Hugger Causes of Increased Particles and Disrupts Operating Room Airflow

i. Bair Hugger Generates Particles

Plaintiffs have offered evidence in the form of Michael Buckôs experiment that confirms the Bair Hugger ï whether previously used or new out of the box ï generates particles.[34] Mr. Buckôs experiments are consistent with peer-reviewed publications.[35]

ii. Bair Hugger Harbors Particles in the Blower

3M admits the Bair Hugger blowers harbor bacteria.[36] As a device known to harbor bacteria, the Bair Hugger increases the bioburden inside the operating room.

iii. Bair Hugger Transports Particles to the Surgical Site

3M agrees all studies confirm that Bair Hugger increases particles over surgical site.[37] That includes internal 3M studies, and studies conducted by qualified, reputable scientists.[38]

Plaintiffs have offered evidence in the form of Elghobashiôs CFD model showing the Bair Hugger transports particles to the surgical site.[39] Elghobashi used an LES CFD

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[34] Ex. 27 (Buck Report).
[35] See Ex. 51 Mark Albrecht, Robert L. Gauthier, and David Leaper, MD, ChM, FRCS, FACS, *Forced-air Warming: a source of airborne contamination in the operating rooms?* ORTHOPEDIC REVIEWS (2009).
[36] Ex. 17 at (291:10-20).
[37] *Id.* at (258:5-13).
[38] *See, e.g.,* Exs. 30, 44, 45, 51, 56, 57, 59, 60. *See also* Ex. 20, (email from Counsel for 3M confirming both Dr. Harper and Dr. Reed are ñprominent researchers in the UKò, both of whom have ï since 2016 - come to serve on a 3M Advisory Board and/or who have been granted funds to support research on the issue of forced-air warming safety.
[39] Ex. 28 (Elghobashi Report).

to model movement of particles through the turbulent air in an operating room.[40] Elghobashi used10 micron particles in his model to simulate larger particles more typically understood to harbor bacteria.[41] Dr. Elghobashi modeled particle movement in turbulent flows, because the airflow in an operating room is indisputably turbulent.[42]

iv. Bair Hugger Increases Bacterial Load at the Surgical Site

A recent study by Oguz et. al. (not associated with Augustine) indicates that the presence of the Bair Hugger increased the bacterial load at the surgical site by 55%.[43] Moretti et. al. also demonstrated an increased bacterial load in an OR when the Bair Hugger was in use, as compared to when the OR was at rest.[44]

C. 3M's "Facts" Cannot Go Uncorrected

1. The BH's "Safety" Record

3M first emphasizes (at 3) that ñPlaintiffs have never presented evidence that any doctor has ever reported that the Bair Hugger system caused his or her patient to develop a surgical site infection.ò As a threshold matter, Plaintiffs are not required to do soð not at this stage of the litigation or any subsequent stage of the case. To defeat 3Môs motion for summary judgment, Plaintiffs need only offer reliable and relevant expert testimony

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[40] *Id.*
[41] *Id.*
[42] Ex. 28 (Elghobashi Rep.). *See also* Ex. 7 (147:15-24)(Bair Hugger creates air currents).
[43] Ex. 52, Oguz, Ruken et al., *Airborne bacterial contamination during orthopedic surgery: A randomized controlled pilot trial*, J CLIN ANESTH , Volume 38 , 160 ï 164.
[44] Ex. 53, Moretti B, Larocca AMV, Napoli C, et al. *Active Warming Systems To Maintain Perioperative Normothermia In Hip Replacement Surgery: A Therapeutic Aid Or A Vector Of Infections*? J HOSP INFECT (2009); 73:58-63. *See also* Huang.

regarding general causation. Any additional evidenceð such as the alleged ñfactsò that 3M emphasizesð is neither here nor there.

3M also misrepresent (at 3) the Bair Huggerôs so-called ñlongstanding track record of safety.ò 3Môs internal documents show [redacted] ò[45] In fact, hundreds if not thousands of doctors refuse to use the Bair Hugger based on the very same concerns raised by Plaintiffsô experts, including Stonningtonð one of Plaintiffsô medical experts; not to mention that 3Môs own documents [redacted].[46] [redacted][47] [redacted][48] [redacted] ò[49] In light of

[45] Ex. 21 (3MBH01485746).
[46] *See, e.g.*, Ex. 22 (3MBH00556461).
[47] *Id.*
[48] *See* Ex. 23 (3MBH00144055).
[49] *See* Ex. 24 (3MBH01260231).

[redacted][50]

2. *Studies Show Bair Hugger is NOT Associated with a Decrease in Surgical Site Infections*

For nearly thirty years, the manufacturers of Bair Hugger have inappropriately extrapolated from underpowered studies in unrelated surgical areas in order to market the product as ñsafeò for use for every surgery patient.[51] 3M has willfully ignored admonition from study authors that testing results in a small urogynecological patient sample are not appropriately transferrable to orthopedic surgery patients.[52] The message, however, was unquestionably received by Defendants. [redacted][53]

Despite these admissions, and in the face of study after study being published disproving any link between preventing intraoperative hypothermia and any reduction in surgical site infection ï including a recent study by the Mayo Clinic[54] - 3M continues to

[50] *See* Ex. 25 (3MBH00814685); *see also* Ex. 26 (3MBH01975265) (Korean government expresses concern about Bair Hugger warming).
[51] *See, e.g.,* http://safepatientwarming.com/spw/index.html (last visited October 3, 2017).
[52] Ex. 54 (Kurz dep.).
[53] See Ex. 2.
[54] Ex. 55, Brown, Michael J., et.al., *Intraoperative Hypothermia and Surgical Site Infections in Patients with Class I/Clean Wounds: A Case Control Study*, J. AM. COLLEGE

this day to perpetuate propaganda about state of medical literature: both as to safety and necessity of the product.[55]

D. FDA Safety Communications

3M also touts (at 3-4) the supposed fact that the ñFDA has never issued any safety communication, warning letter, or taken any other enforcement action related to an infection purportedly caused by the Bair Hugger system.ò [redacted]. Nor does 3M mention that FDA actions do not impact the ñreliability of [P]laintiffsô expertsô causation opinionsò one way or another, *Glastetter*, 107 F. Supp. 2d at 1035ï 36, or that many other agencies such as the Centers for Disease and Control have warned that ñ[n]othing that blows air should be in an operating theatre.ò[56] Even ECRIð the same ñindependent medical organizationò that 3M repeatedly references in its motion for summary judgmentð recently proclaimed that patient-warming devices ñshould have HEPA-grade or better air filters to reduce the risk that airborne dust, bacteria, and mold will be blown onto the patient or into wounds.ò[57] 3M not only fails to mention that the Bair Hugger does not haveð and has never hadð such a filter, but it also makes no mention of the fact that it waited until 2016 to correct the FDAôs misunderstanding that

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SURG. (2016) (finding no reduction in SSI associated with prevention of intraoperative hypothermia in patients with clean wounds).

[55] See Ex. 29.

[56] *See* Ex. 31, HICPAC, Record of Proceedings, Nov. 5-6, 2015 at 27.

[57] See Ex. 32 (ECRI).

the Bair Hugger had HEPA filtration.[58] Long before that time, [redacted] ò[59]

E. Surgical Infections is a Known Risk

To the extent 3M further contends (at 4) that ñsurgical infections are a known surgical complication with many possible causes specific to each patient,ò 3M appears to have it backwards. At this stage of the litigation, Plaintiffsô experts have only testified as to general causation, not specific causation. And at this stage of the litigation, 3M has only moved to exclude expert testimony relating to general causation, not specific causation. 3M thus cannot put the cart ahead of the horse by arguing that the cause of infection is specific to each patient. Further, 3M seems to suggest that liability cannot attach if the harm in question may be caused by other modalities. Under this rationale, tobacco companies would never have liability for hiding the known risk of lung cancer because lung cancer can develop without exposure to tobacco products, and likewise, the New England Compounding Center would have no liability for distributing contaminated injections because meningitis can be transmitted in college dorms as well. This absurd logic is divorced from the American justice system.

[58] *See* Ex. 33 (2016 letter to FDA).
[59] *See* Ex. 34 (3MBH01617179).

F. 3M's Proffered Infectious Disease Expert Excluded Other Sources of Infection in the Operating Room

At his deposition, Dr. Richard Wenzel excluded other operating room equipment as potential sources of contamination in the operating room. Wenzel excluded the anesthesia machine.[60] Wenzel excluded the surgical lights.[61] Wenzel excluded the computer monitors.[62] Wenzel excluded the computer console,[63] the electro-cautery device,[64] and the bovie.[65] He excluded the surgical drapes,[66] the cabinets along the walls,[67] and the suction drain.[68] Wenzel also excluded the sterilized surgical equipment,[69] drop buckets,[70] and the trash receptacles.[71] Wenzel excluded the surgeon moving his or her hands.[72]

G. Augustine's Scare Campaign

Finally, 3M beats a dead horse by arguing (at 4) that the thousands of cases in the multidistrict litigation boil down to nothing more than a byproduct of Augustineôs ñscare campaign.ò But as Plaintiffs have made clear at each and every turn of this litigation, 3Môs narrative is a fiction. 3Môs true fears were summarized in a clandestine strategy

[60] Ex. 7, Wenzel Dep. (99:4-11).
[61] *Id.* at (99:19-24).
[62] *Id.* at (99:25-100:4).
[63] *Id.* at (100:5-12).
[64] *Id.* at (100:13-16).
[65] *Id.* at (100:18-23).
[66] *Id.* at (100:24-101:5).
[67] *Id.* at (101:6-10).
[68] *Id.* at (101:11- 18).
[69] *Id.* at (102:7-14).
[70] *Id.* at (103:3-7).
[71] *Id.* at (103:8-11).
[72] *Id.* at (103:12-104:2).

meeting known [redacted] ò[73] [redacted] ò[74] Whatôs more, none of Plaintiffsô claims in this litigation relate in any way to Augustineôs so-called ñscare campaign.ò To the contrary, Plaintiffs rely on independent scientific evidence, including peer-reviewed and published studies, along with the opinions of a world-class epidemiologist (Samet), renowned infectious disease expert (Jarvis), skilled surgeon (Stonnington), and an engineer who is at the very top of his field (Elghobashi). This is sound science. And faced with this sound science, 3M focuses on conspiracy theories in the hopes of diverting the Courtôs attention, all the while 3M continues to subject perhaps 50,000 patients to this dangerous product *every single day*.

III. LEGAL STANDARD

Summary judgment is improper if there are disputed issues of material fact. Fed.R.Civ.P. 56(c). The Court ñmust view the evidence and inferences that may reasonably be drawn from the evidence in the light most favorable to the nonmoving party.ò *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 950, 968-69 (D. Minn. 2009)(citing *Enterprise Bank v. Magna Bank,* 92 F.3d 743, 747 (8th Cir.1996)).

[73] *See* Ex. 35 (3MBH00053468).
[74] *Id.*

The moving party bears the burden of showing that there is no genuine issue of material fact and that it is entitled to judgment as a matter of law. *Enterprise Bank,* 92 F.3d at 747. *DLH, Inc. v. Russ*, 566 N.W.2d 60, 71 (Minn. 1997).

A party opposing a properly supported motion for summary judgment may not rest on mere allegations or denials, but must set forth specific facts in the record showing that there is a genuine issue for trial. *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 256 (1986); *Krenik v. Le Sueur,* 47 F.3d 953, 957 (8th Cir. 1995). The facts and evidence submitted in support of this memorandum, along with the facts and evidence submitted in support of the memorandums opposing Defendantsô *Daubert* motions establish a record chockfull with specific facts that must be resolved by the jury. Summary judgment is inappropriate. Causation is generally a question of fact for the jury. *Paidar v. Hughes*, 615 N.W.2d 276, 281 (Minn. 2000).

IV. ARGUMENT

A. Plaintiffs Have Offered Qualified, Reliable, Relevant Expert Testimony in Support of Their Claims

Plaintiffs have disclosed expert reports from qualified experts, each of whom offer reliable relevant testimony and opinions on the issues of general causation.

1. Plaintiffs' Claims Which Require Proof of Causation are Properly Supported

a) Plaintiffs Have Offered Medical Expert Testimony Establishing Causation

Relying on *Turner* and other Eighth Circuit cases, 3M (at 8) advances the unremarkable position that ñthe cause of medical injuries requiring surgical intervention or other highly scientific technique for diagnosis . . . is not within the realm of lay

understanding and must be established through expert testimony.ò Rather than cabin its argument to that rule, 3M obfuscates the distinction by declaring that ñmedical expertò testimony is required in ñevery jurisdiction.ò To be sure, the *Lipitor* courtð like all courtsð recognized that expert testimony is necessary ñwhere the issues are medically complex and outside common knowledge and lay experience,ò *In re Lipitor Mktg., Sales Pracs. & Prods. Liab. Litig.*, 227 F. Supp. 3d 452, 469ï 77 (D.S.C. 2017), but that does not mean that other types of expert testimony cannot support general causation. The REFERENCE MANUAL ON SCIENTIFIC EVIDENCE makes clear that Elghobashiôs opinions, for example, may be used to show the mechanism by which the Bair Hugger increases the risk of infection; that is, the way in which the device increases particles and thus bacteria over the surgical site. REFERENCE MANUAL ON SCIENTIFIC EVIDENCE, 3d ed. at 552, 604 (Federal Judicial Center 2011) (concluding that the mechanistic evidence ñlends credence to an inference of causalityò); *see also Kruszka v. Novartis Pharm. Corp.*, 28 F. Supp. 3d 920, 940 (D. Minn. 2014) (allowing testimony on ñplausible causation mechanismò despite defendantôs objection).

b) General Causation Opinions—Epidemiology vs. Other Methods

Finally reaching the merits of its motion, 3M (at 11) incorporates by references the arguments made in its *Daubert* briefs[75] and then cursorily contends that the causation

[75] Plaintiffs follow suit, incorporating by reference the arguments made in their *Daubert* motions to exclude Drs. Theodore Holford (Doc. 801)and Jonathan Borak (Doc. 778), along with the arguments made and evidence offered in opposition to 3Môs *Daubert* motions to exclude Plaintiffsômedical (Doc. 879)and engineering (Doc. 914)experts.

testimony of all three of Plaintiffsô medical experts depends on the McGovern study. Defendants are incorrect.

While the McGovern study (discussed *infra* at 21-32) quantifies the magnitude of the increased risk from Bair Hugger, it is not the only evidence Samet, Jarvis, or Stonnington considered in drawing causal inference. Samet, for example, made clear at his deposition that the McGovern study allowed him to ñquantify the magnitudeò of the risk but that he relied on ñdifferent lines of evidenceò in determining the Bair Hugger causes deep joint infections.[76] *See also Ambrosini v. Labarraque*, 101 F.3d 129, 136 (D.C. Cir. 1996) (ñepidemiologists evaluate the totality of the dataò). 3M admits as much in its briefing based on its apparent understanding of ñquantify[ing] the alleged riskò versus drawing causal inference.[77] *See also* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE at 568 (ñThe odds ratio (óORô) is similar to a relative risk in that it expresses in quantitative terms the association between exposure to an agent and a disease.ò) (emphasis added).

Second, even if the McGovern study did not exist or if Plaintiffs did not rely on it, the same Eighth Circuit decision 3M repeatedly cites in support of its motion actually recognizes the ñabsence of epidemiological evidenceò does not doom Plaintiffsô case. *See Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 992 (8th Cir. 2001)). Plaintiffs may rely on a myriad of methods to show causation. *See, e.g., In re Berg Litig.*, 293 F.3d 1127, 1130 (9th Cir. 2002) (ñNor is epidemiologic evidence the sole method of

[76] Ex. 41, Samet Dep. (166:20-167:22); Ex. 43 (Samet Rept.) at 21, Fig. 3.
[77] Defs.ô Mem. at 11.

establishing causation.ò) (citing *Glastetter*, 252 F.3d at 992); *In re Joint E. & S. Asbestos Litig.*, 964 F.2d 92, 97 (2d Cir.1992) (plaintiff relied on clinical evidence as well as epidemiological studies to prove causation); *In re Paoli R.R.Yard PCB Litig.*, 35 F.3d 717, 758 (3d Cir.1994) (discussing differential diagnosis as a method of assessing causation); *Caraker v. Sandoz Pharm. Corp.*, 188 F.Supp.2d 1026, 1033 (S.D. Ill. 2001) (ñ[t]his Court imposes no absolute epidemiology requirementò). 3Môs broad attack on the McGovern study is thus misplaced.

c) Attacks on the McGovern Study Are Unfounded

Nor do 3Môs specific challenges to the McGovern study pass muster. While all of 3Môs arguments have been addressed and rebutted in related submissions, Plaintiffs will briefly reiterate those arguments here with cross-references as necessary.

(1) The "Authors Disclaim Causation" Argument

3M first asserts (at 11) that the McGovern study is ñunreliableò because its authors ñexpressly disclaimed any finding that the Bair Hugger system causes surgical site infections.ò. This argument is unavailing for two reasons:

First, because epidemiologic studies can establish only an association between exposure and outcomes, authors of observational studies are cautious to find causation based on an association, ñoften calling for stronger evidence and more research before a conclusion of causation is drawn.ò *See id.* at 598ï 99. The fact that the McGovern authors did not find causation is therefore hardly surprising; McGovern et. al. were conducting limited experiments to add data to the scientific conversation. The McGovern study authors include a group of well-respected orthopedic surgeons, statisticians, and

anesthesiologists, some of whom have taught and still teach at the University of Minnesota and the Carlson School of Business. Despite their credentials to determine whether an *association* exists between the Bair Hugger and deep joint infections, the authors are not epidemiologists and thus do not have expertise in making the ultimate determination with respect to causal inference. The authors thus did not opine on all the scientific evidence available in 2011 at the time they published the study or the burgeoning body of research since then. Nor did they consider any method for drawing causal inference such as the Bradford Hill criteriað and for good reason. That is the job of epidemiologists such as Dr. Samet, infectious disease specialists such as Dr. Jarvis, and clinicians such as Dr. Stonington who review the totality of evidence and render causal conclusions. As the REFERENCE MANUAL ON SCIENTIFIC EVIDENCE explains: ñDrawing causal inference after finding an association and considering [the Bradford Hill] factors requires judgment and searching analysis, based on biology, of why a factor or factor may be absent despite causal relationship.ò *Id.* at 600. Causal determinations thus depend on the expertise and judgment of Plaintiffsô expertsð a fact 3Môs experts conceded at their depositions.[78]

Second**,** to the extent 3M argues the McGovern study contradicts the opinions of Plaintiffsô experts, which it does not, the validity of these opinions are for the jury to decide because all of Plaintiffsô experts followed reliable and well accepted

[78] *See, e.g.*, Ex. 36, Holford Dep. (374:7-376:10).

methodologies.[79] *See also Bonner v. ISP Technologies, Inc.*, 259 F.3d 924, 932 (8th Cir. 2001) (affirming admissibility of expert testimony even though expert relied on study with different result); *In re Viagra Prods. Liab. Litig.*, 572 F. Supp. 2d 1071, 1081-82 (D. Minn. 2008) (concluding contradictory studies did not undermine expertôs testimony because ñquestions of conflicting evidence must be left for the juryôs determination); *In re Celexa and Lexapro Prods. Liabl. Litig.*, 927 F. Supp. 2d 758, 764 (E.D. Mo. 2013) (rejecting defendantôs argument that plaintiffsô causation expert could not rely on a study that reached the opposite conclusion). Tellingly, 3M fails to cite any controlling authority which would preclude an expert from such reliance, instead relying on single case out of the Fifth Circuit that has been heavily criticized since its inception. *See, e.g.*, *Doe 93 v. Sec'y of Health & Human Servs.*, 98 Fed. Cl. 553, 569 (2011) (criticizing district courtôs reliance on *Huss v. Gayden*, 571 F.3d 442, 459 (5th Cir. 2009), because the court ñexceeded the proper role of a gatekeeperò by rejecting evidence that did not conclusively prove causation, thus elevating the burden of proof).

At bottom, 3Môs argument is ñwholly inconsistent with *Daubert* and the fundamental premise of Rule 702.ò *See McClellan v. I-Flow Corp.*, 710 F. Supp. 2d 1092, 1101 (D. Or. 2010); *see also In re Heparin Prods. Liab. Litig.*, 803 F. Supp. 2d 712, 733-74, 742 (N.D. Ohio 2011) (concluding reliance on studies that do not establish causation to a certainty do not render opinions ñjunk science.ò); *Monroe v. Zimmer U.S. Inc.*, 766 F. Supp. 2d 1012, 1027 (E.D. Cal. 2011) (concluding studies which do not

[79] *See generally* (Doc. 879)

prove causation may still be used to inform an expertôs opinion on general causation); *In re Pheylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1239 (W.D. Wash. 2003) (rejecting defendantôs criticism of epidemiologic studies).

(2) Study Authors Disclosed "Confounding Factors."

3M next asserts (at 11) that the ñconfounding factors disclosed in the McGovern study account entirely for the purported association between Bair Hugger use and increased infections.ò[80] This argument was addressed and rejected in Plaintiffsô motion to exclude the expert testimony of Theodore Holford.[81]

First, as explained in Plaintiffsô Motion to Exclude Holford, and in the expert reports of Drs. Samet, Jarvis, and Stonington, neither the change in thromboprophylaxis or antibiotic during the McGovern study confounded the association between Bair Hugger and deep joint infections.[82] Professor Holford admitted as much at his deposition, conceding the scientific literature does not suggest a relationship between thromboprophylaxis drugs and deep joint infections.[83] Nor did he or 3Môs other experts offer any good reason for ignoring the great weight of scientific literature reaching the opposite conclusion.[84] Without an *a priori* basis to determine the change in thromboprophylaxis drugs confounded the McGovern study, 3M and its ñexpertsò have

[80] Defs.ô Mem. at 11 (Doc. 762).
[81] (Doc. 801)
[82] *Id.* at 21ï 30.
[83] *See* Ex. 36, Holford Dep. (293:7-295:13).
[84] *See* Doc. 801 at 24ï 25 (collecting peer-reviewed studies showing no significant relationship between deep joint infection and thromboprophylaxis drugs).

simply fabricated a connection for purposes of this litigation.[85] But science, in stark contrast to patient warming devices, cannot be so easily manufactured.

Second, 3Môs argument regarding the change in antibiotic fails for the same reasons. In addition to the deposition testimony of the study authors, the scientific literature finds ñno clear benefit to using one particular antibiotic agentò versus another for purposes of preventing deep joint infections.[86] Holford, moreover, admitted at his deposition that the change in antibiotic from gentamicin to gentamicin plus teicoplanin actually reduced infection rates among patients who used the Bair Hugger and increased infection rates among patients who used other warming devices.[87] If anything, then, Holfordôs calculations suggest that the increased risk of Bair Hugger warming may be even greater than the 3.8 odds ratio reported in the McGovern study.[88]

Third, due to the holes in 3Môs expert testimony, 3M reverts (at 11-12) to misrepresenting the nature of Mr. Albrechtôs deposition testimony, which he provided in a non-expert capacity. 3M represents that Mr. Albrecht admitted ñthere was no statistically significant increase in infection rates when the change in drug regimen is accounted for.ò[89] 3M not only fails to cite the transcript, thereby failing its burden on summary judgment, but it omits Mr. Albrechtôs additional testimony. While Mr. Albrecht recognized the infection rates were similar when the drug regimen was controlled, he also

[85] *See id.* at 26.
[86] *Id.* at 27ï 28.
[87] *See id.* at 28 (citing Holford Dep. at 317:2-322:14).
[88] *See* Ex. 37 (Holford Rpt.) at 6 (calculating higher DJI rate from gentamicin plus teicoplanin than gentamicin).
[89] Defs.ô Mem. at 12.

testified there were ñnot enough infectionsò in such a small population to be ñproperly powered.ò[90] Doctor McGovern and Professor Nachtsheimð a statistics professor at the Carlson School of Management at the University of Minnesotað reached the same conclusion.[91] So too did 3Môs expert, Dr. Holford, who conceded controlling for both variables resulted in unpredictable and unreliable conclusions.[92] Given these factual disputes, 3M cannot prove the ñconfounding factors disclosed in the McGovern study account entirely for the purported association between Bair Hugger use and increased infections.ò[93]

(3) False Allegations of "Undisclosed" Confounding Factors

3M next argues (at 12) that other ñmajor undisclosed factors affectedò the McGovern study. Yet 3M fails to discuss, much less cite, a shred of evidence to support its *ipse dixit*. Nor can it. As discussed in Plaintiffsô motion to exclude the testimony of Drs. Holford and Borak, these variables were not identified in the McGovern study for a straightforward reason: while they might impact surgical site infections, they have no

[90] See Ex. 38, Albrecht Dep. (217:13-218:4) (ñThis data, thereôs possibly not enough infections ï infections to do a multivariate analysis like that where itôs properly powered.ò).
[91] *See* Ex. 39, Nachtsheim Dep. (340:5-11; 349:19-25); *see also* Ex. 40, McGovern Dep. (385:4-14) (finding no reason to ñdeselect patients from the population presented in this study for those who received a different type of antibiotic than othersò).
[92] *See* Doc. 801 at 29 (citing Holford Dep. at 325:8-326:1).
[93] Def. Mem. at 11 (emphasis added).

impact on deep joint infections.[94] 3M cannot repair this fatal error, especially given the admissions of its own ñexperts.ò[95] Accordingly, 3Môs arguments must be ignored.

(4) Accusations of "Tabulation Error"

3M next contends (at 12) Professor Holford ñdemonstratedò that the McGovern study ñsuffers from major tabulation errors.ò[96] Defendantsô argument is contradicted by Holfordôs deposition testimony. In contrast to his expert report, Holfordôs deposition testimony reveals that he did not use the final data underlying the McGovern study to determine whether the study suffered from ñmajor tabulation errors.ò[97] Failing to conduct any independent research, Holford instead relied on a draft data set that he received from 3Mð among only 19 other documentsð and simply took the numbers at face value.[98] Given the dearth of his knowledge on the subject, much less the McGovern study itself, Holford conceded that he did not know whether that the data he relied for purposes of his testimony were the same data the authors used in publishing the study.[99] At best, Holford only knew that the draft data set he used in each of his calculations was incomplete and different from the data actually used in the published and peer-reviewed study.[100] For

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[94] *See* Doc. 801 at 22-23; Doc. 778 (Pls.ô Mot. to Exclude Borak) at 9-10, 18-20.
[95] *See* Ex. 36 Holford Dep. (304:13-306:10)(admitting that deep joint infections are ñnot the same thingò as surgical site infections).
[96] *See* Defs.ô Mem. at 12.
[97] *See* Doc. 801 at 9ï 11.
[98] *Id.* at 9.
[99] *Id.* at 9 (internal citations omitted); *see also id.* at 10 (admitting that the data he relied on contradicted the data provided in Figure 7 of the McGovern study (internal citations omitted).
[100] *Id.* at 9. 3Môs expert testimony therefore dooms its own argument. *See also id.* at 11 (compiling deposition testimony from authors that there were no tabulation errors)

these reasons, along with the arguments stated in Plaintiffsô motion to exclude the testimony of Dr. Holford,[101] 3Môs reliance on *In re Viagra*, 658 F. Supp. 2d at 944-45, is clearly misplaced.[102]

To the extent 3M cites Sametôs deposition testimony for the erroneous proposition that Holford ñdid the calculations correctly,ò once again Defendants misrepresent evidence to this Court.[103] In the cited portion of his deposition, Samet wasnôt referring to the flawed inputs, data, or methods underlying Holfordôs calculations. The full deposition transcript clearly shows Samet was only referring to the single calculation in ñFootnote 1ò of Holfordôs report.[104] Along with ignoring the context of Sametôs testimony, 3M further disregards what Holford actually found in ñFootnote 1.ò The calculation therein not only not only shows a significant relationship between use of the Bair Hugger and deep joint infections (p=.0356), but it also shows at least a doubling of the risk from using the device in orthopedic surgeries (OR=2.86).[105] Reed explained as much at his deposition.[106] For these reasons, among others discussed in Plaintiffsô *Daubert* motions, numerous disputes of fact preclude the Court from granting 3Môs motion for summary judgment.

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[101] Doc. No. 801.
[102] *See* Defs.ô Mem. at 13 (citing *Viagra I* for the proposition that an epidemiological study was not reliable because ñplaintiffs failed to rebut miscodings and errorsò).
[103] *Id.*
[104] *See* Ex. 41. Samet Dep. (125:23-126:7) (asking whether Samet ñhad any reason to think that Holford screwed up the calculations that he did thereò) (emphasis added).
[105] Ex. 37 at 2.
[106] Doc. 801 at 11 (noting that adding or subtracting a single deep joint infection from the McGovern study does not impact the ñscientific, human, or economicò significance of the study).

(5) Contentions about Background Risk

3M (at 13) further asserts the McGovern study ñdoes not compare the Bair Hugger system against background risk to the general population of orthopedic patients.ò[107] No such requirement exists in this Circuit, and 3M cites none. The only case it does citeð *McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233 (11th Cir. 2005)ð not only hails from a foreign jurisdiction, but it unremarkably states a ñreliable methodology should take into account the background risk.ò *Id.* In reaching that determination, the Eleventh Circuit relied on a toxicology article by David Eaton. *Id.* at 1234. But that article says nary a word about ñbackground riskò and states the analysis of ñother known causesò does not necessarily apply to general causation. *See* D. Eaton, *Scientific Judgment and Toxic Torts—A Primer in Toxicology for Judges and Lawyers*, 12 (1) J LAW & POLICY 5, 40 (2003). Moreover, while ñbackground riskò might be helpful in certain cases and academic situations, it is inapposite here. 3Môs own expert acknowledged in his report that ñthe use of intraoperative warming has become a standard of current surgical care.ò[108] The more appropriate question, then, is whether the Bair Hugger, as compared to other patient-warming devices and/or methods, increases the risk of deep joint infection in orthopedic patients. Samet considers this inquiry head-on in finding causation.[109] And lest 3M forget, its own experts have disavowed the very argument it now raises here.

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[107] Defs.ô Mem. at 13.
[108] *See, e.g.*, Ex. 42 (Borak Rept.) at 3.
[109] *See* Ex. 43 (Samet Rpt.) at 4 (ñthe appropriate counterfactual is either no specific warming device or the use of a warming device that does not involve forced-air, the actual alternatives in practiceò).

Borakôs report expressly states that ñthe hypothetical comparison of BH [Bair Hugger] vs. no warming device is not relevant to this dispute.ò[110] He then avers that ñthe alternative comparison, whether use of BH results in increased rates of SSI compared to use of non-FAW device, all other things being equal, is the central question here.ò[111] 3Môs double-talk is not only dishonest but provides clear and sufficient grounds for denying 3Môs motion.

2. Ruling Out Other Causes

Recognizing the quality of Plaintiffsô scientific evidence, 3M alternatively argues (at 13) that ñeven if [Plaintiffs] did have scientifically compelling evidence to support their opinion that the Bair Hugger system causes surgical site infections, they offer no methodology whatsoever for reliability ruling out the far more likely causesò of infection.[112] Again, based on the same cases cited in its own brief, 3M puts the cart before the horse. *See In re Viagra*, 572 F. Supp. 2d at 1075 (general causation ñbears on whether the type of injury at issue can be caused or exacerbated by the defendantôs product,ò while specific causationò bears on whether, in the particular instance, the injury actually was caused or exacerbated by the defendantôs product.ò); *Glastetter v. Novartis Pharmaceuticals Corp.*, 107 F. Supp. 2d 1015, 1027 (E.D. Mo. 2000) (noting that ñwhile differential diagnosis is important and an accepted methodology with respect to issues of óspecific causation,ô such diagnosis may not be helpful with respect to ógeneral

[110] Ex. 42 at 3.
[111] *Id.* (emphasis added).
[112] *See* Defs.ô Mem. at 13.

causationò). Not to mention that Sametôs use of the ñsufficient component cause frameworkò aptly ñcaptures multicausality in the existence of several causal [factors],ò[113] while Holford conceded that the odds ratio reported in the McGovern study is enough to prove ***specific causation***.[114] *See also In re Viagra*, 572 F. Supp. 2d at 1078 (ñconclud[ing] that an RR [risk ratio] of 2.0 or greater provides reliable evidence of specific causationò) (emphasis added); *cf.* REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 3d. at 616 (ñ[A] plaintiff may satisfy his or her burden of production even if a relative risk less than 2.0 emerges from the epidemiologic evidence.ò). Thus, even at this early stage, the Court should deny 3Môs request for summary judgment on specific causation.

3. Conclusion

In the final analysis, the McGovern article is a published and peer-reviewed epidemiological study that directly investigated the association between deep joint infection and the Bair Hugger. It reported a statistically significant 3.8 fold increased risk of infection from the Bair Hugger compared to conductive warming blankets. As is routinely done in peer-reviewed literature, the authors described the methods they used and their findings. The article grew out of pre-litigation research, passed peer review, and was published in a respected medical journal; it has never been retracted. Nor has 3M, Holford, Borak, or any other witness called for its retraction. There are no

[113] Ex. 43 at 6.

[114] Ex. 36 (225:19-226:2) (agreeing to the proposition that ñif the incidence of disease in an exposed group is more than twice the incidence in the unexposed group [i.e., OR > 2.0], the probability that exposure to the agent caused [the same disease] in a similarly situated individual is also greater than 50%ò).

epidemiological studies that contradict or disprove the association between the Bair Hugger and deep joint infection as reported in the study. Publication in a reputable peer-reviewed journal shows the study meets ñat least the minimal criteria of good science.ò *Daubert v. Merrel Dow Pharmaceuticals Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995). Because epidemiologic studies have been well received by federal courts in mass tort suits, *see, e.g.*, *In re Viagra*, 572 F. Supp. 2d at 1081, and Plaintiffs have both legally and factually rebutted 3Môs ñex post factoò attacks, *see In re Phenylpropanolamine Prods. Liab. Litig.*, 289 F. Supp. 2d at 1240, 3M is not entitled to summary judgment. In fact, even if Plaintiffs did not have the McGovern study, 3M would not be entitled to relief. *Glastetter*, 252 F.3d at 992 (ñThe absence of epidemiological evidence did not doom Plaintiffôs case.ò).

B. For Certain Claims Asserted by Plaintiffs, Proof of Causation is Unnecessary

Citing cases such as *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d at 968, 3M initially argues that all of Plaintiffsô claims require proof of causation.[115] Not so. Even *In re Viagra* recognized that ñunjust enrichment claim[s] do[] not explicitly require a showing of causation,ò yet 3M blithely ignores that dispositive distinction. As this Court recognized in the same case that 3M cites, causation is not an element of unjust enrichment. *See id.* at 969 (citing *Southtown Plumbing, Inc. v. Har-Ned Lumber Co., Inc.*, 493 N.W.2d 137, 140 (Minn. App. 1992) (ñTo establish an unjust enrichment claim it must be shown that a party has knowingly received something of value, not being entitled

[115] Defs.ô Mem. at 6ï 7.

to the benefit, and under circumstances that would make it unjust to permit its retention.ò)). The vast majority of MDL courts have reached the same conclusion that causation is not necessary for proving such claims. *E.g.*, *In re ConAgra Foods, Inc.*, 90 F. Supp. 3d 919, 990 (C.D. Cal. 2015) (ñcausation, materiality, and reliance are not explicit elements of an unjust enrichment claimò); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 2012 WL 3154957, at *9 (N.D. Cal. Aug. 2, 2012) (ñUnjust enrichment does not require the same type of showing of causation or reliance.ò).

Nor has 3M cited any authority imputing the element of causation on the consumer protection claims alleged in Plaintiffsô Master Long Form Complaint; instead, it yet again disregards both binding and contrary authority. *See Group Health Plan, Inc. v. Phillip Morris Inc.*, 621 N.W.2d 2 (Minn. 2001) (consumer fraud statutes loosen causation and allow consumers to show direct or indirect injury through a multitude of evidence); *see also* Wilson & Gilmer, *Minnesota's Tobacco Case: Recovering Damages Without Individual Proof Of Reliance Under Minnesota's Consumer Protection Statutes*, 25 WM. MITCH. L. REV. 567, 591 (1999) (consumer protection statutes allow consumers to show direct or indirect injury through: (1) consumer and expert testimony; (2) consumer reactions to the fraud; and (3) evidence of corporate actions and intentional deceit). So even if Plaintiffsô negligence, strict liability, and warranty claims require proof of causation, other claims do not. 3Môs motion thus unravels from the start.

C. Engineering Experts

Without addressing, let alone denting, the expert conclusions of Drs. Samet, Jarvis, and Stonington, 3M reverts to criticizing the expert testimony of Plaintiffsô

engineering experts.[116] These challenges are equally unavailing, and seemingly irrelevant given Defendantsô motion is premised exclusively on the assertion that Plaintiffsô medical experts should all be excluded. Lest the Court consider any of the dicta in Defendantsô memorandum, Plaintiffs are compelled to touch on the flaws in Defendantsô attempted analysis regarding Plaintiffsô engineering experts.

1. Flawed Augustine Research

3M first argues that Plaintiffsô engineering experts are inadmissible because their opinions depend on ñdeeply flawed órearchô conducted by and on behalf of Dr. Scott Augustine and his cohorts.ò[117] While Plaintiffsô response to 3Mõs motion to exclude engineering experts debunks this argument, one point above all deserves reiteration: The studies that 3M attacks were not only conducted by reputable scientists[118] and published in in reputable scientific journals, but many of the peer-reviewed studies had nothing to do with Augustine. The 2013 study by Legg and Hamer, for example, found that ñconvection currents [from the Bair Hugger] increased particle concentration 1000-fold by drawing potentially contaminated particles from below the operating table into the surgical site.ò[119] The study makes clear that ñ[n]o benefits in any form [were] received from a commercial party directly or indirectly relating to the subject of this article.ò[120] Nor were any of the study authors employed by Augustine or his entities. Legg testified

[116] Defs.ô Mem. at 14.
[117] *Id.*
[118] See Ex. 20.
[119] *See* Ex. 45 (Legg 2013).
[120] *Id.*

that he drafted the paper and conducted the research separate and apart from Augustine.[121] The 2012 study by Legg and Hamer likewise found that the Bair Hugger significantly increased the number of particles over the surgical field, ñwhich raises concerns as bacteria are known to require particles for transport.ò[122] There, too, the authors had no personal or professional relationship with Augustine. Disclaiming receipt of any benefits, the authors independently designed, conducted, and published their clinical experiment.[123] The same holds true for a slew of other studies that predate Augustineôs departure from the company.[124] Viewed independently or collectively, these independent articles disprove 3Môs first argument.

2. "Scientifically Convincing" Standard

Relying on *Glastetter*, 3M next contends (at 14) that Plaintiffsô engineering experts have not provided ñscientifically convincing evidence.ò As explained in Plaintiffsôresponse to 3Môs motion to exclude medical experts, 3M not only misstates the legal standard for expert testimony; it also misreads *Glastetter*. The *Daubert* standard for analyzing expert testimony applies equally to all types of expertsð no matter whether

[121] *See* Ex. 46, Legg Dep. (65:11-25, 81:18-25).
[122] Ex. 44 (Legg 2012).
[123] *See* Ex. 46, Legg Dep (39:22-24;42:3-16).
[124] *See, e.g.*, Ex, 47 (Avidan)(concluding that the Bair Hugger is a ñpotential source of nosocomial infection); Ex. 48 (Baker)(finding ñinsufficient evidence to justify the routine use of forced air warming units as an interoperative measure during ultraclean orthopaedic surgeryò due to patient risk from ñcontaminated airò and ñeffect on airflow in ultraclean ventilation systems.ò); Ex. 49 (Bernards)(finding bacteria inside Bair Hugger was linked to outbreak of nosocomial infections while concluding the device may act ñas a secondary source of transmission.ò); Ex. 50 (Gjolaj)(finding internal contamination and declaring that the Bair Hugger ñmay blow contaminated air.ò).

they are medical experts or engineering experts, and no matter whether they express opinions on scientific or other technical matters. *See, e.g.*, *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149 (1999) (declaring the same flexible standard under Rule 702 grants latitude ñto all experts, not just óscientificô onesò). As long as the testimony falls within the ñrange where experts might reasonable differ,ò it should not be excluded under Rule 702. *Id.* at 153. To demand that testimony be based on a ñconvincingò evidence even where reasonable experts can disagree would accomplish only one thing: elevating Plaintiffsô burden of proof. *See, e.g.*, *In re Ephedra Prods. Liab. Litig.*, 393 F. Supp. 2d 181, 188 (S.D.N.Y. 2005) (citing *Kumho Tire Co.*, 526 U.S. at 148). Precisely for that reason, *Glastetter* did not set a different standard for evaluating the testimony of one type of expert versus another. The Eighth Circuit merely affirmed the exclusion of plaintiffôs expert becauseð unlike hereð there was no reliable evidence of causation. *See Glastetter*, 252 F.3d at 990-91; *Johnson*, 754 F.3d at 563 (distinguishing *Glastetter* on the grounds that the expert relied on ñunreliableò information); *In re Viagra Prods. Liab. Litig.*, 572 F. Supp. 2d at 1081 (concluding that *Glastetter* was not controlling because the data involved conditions that were ñquite distinctò from the health outcome at issue). In fact, the Eighth Circuit rejected the very standard touted by 3M, noting that the absence of direct evidence does not doom causation. *See* 252 F.3d at 992. Not to mention that neither the Eighth Circuit nor any other court within this jurisdiction has interpreted *Glastetter* as imposing a more exacting standard of reliability for general (or specific)

causation. Tellingly, Defendants cite none.[125] *See also In re Viagra Prods. Liab. Litig.*, 572 F. Supp. 2d at 1080 (holding that general causation expertôs reliance on studies lacking ñstatistical significanceò did not require exclusion). *See also Schroeder v. St. Louis County*, 708 N.W.2d 497, 507 (Minn. 2006) (describing ósubstantial evidenceô as ñincorrect legal standardò and clarifying that ñsummary judgment is inappropriate if the nonmoving party has the burden of proof on an issue and presents sufficient evidence to permit reasonable persons to draw different conclusionsò).

3. Particles vs. Bacteria

Based on this improperly elevated standard, Defendants contend that ñPlaintiffsô experts never conducted any tests to determine whether use of the Bair Hugger causes an increase in bacteria at the surgical site.ò[126] This is false. Elghobashi used computational fluid dynamics modeling to determine how the Bair Hugger impacts air movement within an operating room and the consequences for distribution of human skin cells during operation.[127] The results of his simulation are clear: ñ[O]perating a Bair Hugger device alters air flow and increases the numbers of squames reaching critical sites relevant to infection risk, including the surgical site and the side tables.ò[128] This finding is important because: (1) ñbacteria typically colonize on human skin cells or squames which are routinely shed by humans,ò[129] (2) particles are a proxy for bacteria,[130] and (3) it only

[125] Defs.ô Mem. at 14.
[126] *See* Defs.ô Mem. at 15.
[127] Ex. 28.
[128] *Id.* at 15.
[129] *Id.* at 1

takes a few bacteria to cause a deep joint infection.[131] In other words, the greater the number of particles, the more bacteria, and the greater the number of bacteria, the greater the risk of deep joint infection. A recent randomized controlled trial by Darouiche et al confirmed this syllogism.[132] The authors found that ñairborne particle counts may be used as a proxy for ambient CFU [colony forming unit] densityò and that ñCFU density at incision sites was significantly related to incidence of implant infection.ò[133] The study thus proves that the skin cells measured in Elghobashiôs study ñdirectly relate to the outcome of interest, deep infection.ò[134] Because ñevery single study indicates that the Bair Hugger increases the particle count over the sterile field,ò[135] it stands to reason that the Bair Hugger increases the risk of deep joint infection.[136] Accordingly, even assuming

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[130] *See* Ex. 8 (concluding that particle counts are significantly associated with bacterial concentration at the surgical site); Ex. 11 (same); Ex. 10(same); Ex. 13 (finding that ñairborne bacteria concentration and [particle mass] concentration followed linear relationships for all the [size] ranges.é The more [particle mass] suspends in the air, the more bacteria exists in the air.ò); Ex. 14 (finding that ñparticle countingé may be used to judge the performance of a clean air operating theatre distribution system, includingé the presence or absence of entrainment of bacteria.ò).

[131] *See* Ex. 43 at 14.

[132] Ex. 11(Darouiche).

[133] Ex. 10 (ICOS).

[134] *See* Ex. 8 (Stocks) (finding particles were significantly related to ñviable microorganismsò that cause surgical site contamination); Raval (ñ[R]educed airborne particulates appear to correlate with a decreased risk of nosocomial infection in high-risk patient populations.ò).

[135] *See* Ex. 17 (258:5ï 10).

[136] *See, e.g.,* Ex. 56, Belani (finding significant increase in neutrally buoyant bubbles and recognizing that ñsmaller airborne particles . . . hav[e] similar airborne characteristics to neutrally buoyant detergent bubblesò); Ex. 44 (Legg 2012) (finding significant increase in ñnumber of particlesò compared to radiant warming, ñwhich raises concern as bacteria are known to require particles for transportò); Ex. 45 (Legg 2013) (finding BH ñincreased the particle concentration 1000-fold . . . by drawing potentially contaminated particles

the applicability of 3Môs elevated standard for evaluating causation, these tests constitute clear and convincing evidence that the Bair Hugger can cause infection.

4. Studies Show Bair Hugger Increases Bacteria in an Operating Room.

So too do a number of studies directly measuring whether the Bair Hugger increases the amount of bacteria in the operating room. Until this litigation, 3M routinely cited the Moretti study, which found a ñsignificantly increased bacterial loadò caused by the Bair Hugger.[137] Tumia et al. reached a similar conclusion, reporting ñhigherò bacterial counts from Bair Hugger use.[138] These studies, among others, directly refute 3Môs claim that ñPlaintiffsô engineering expertsô testimony about the Bair Hugger óharboringô bacteria and influence airflow is nothing more than speculation.ò[139]

5. Augustine Research

3M finally asserts that the ñAugustine researchers tried on multiple occasions to demonstrate an increase in bacteria from use of the Bair Hugger system.ò[140] While 3M accuses the researchers of keeping these results ñsecret,ò just the opposite is true. McGovern (who never worked for Augustine) testified at length that his only attempt to culture bacteria from the Bair Hugger was ñnot a good studyò due to numerous

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from below the operating table into the surgical siteò); Ex. 59 (McGovern) (significant increase); Ex. 60 (Sessler)(nearly significant increase after 15 seconds).

[137] *See* Ex. 53 (Moretti); *see also* Ex. 57 (Wood)(ñMoretti et al. found an increased bacterial load at the surgical site when FAW was used.ò).

[138] *See* Ex. 58 (Tumia) 2002.

[139] Defs.ô Mem. at 15.

[140] *Id.*

methodological issues.[141] Legg (who was also never employed by Augustine) corroborated those issues, testifying about the inherent difficulties of using agar plates to capture bacteria in operating rooms.[142] Unlike McGovern and Legg, Albrecht was employed by Augustine. But his experimentsð which were never published or peer-reviewedð still showed that some bacteria escaped from the Bair Hugger and into the operating room. Albrechtôs *ad hoc* experiments also failed to test the second causal mechanism considered by Plaintiffsô experts; that is, whether the Bair Hugger disrupts airflow in the operating room. None of these informal tests thus disprove the conclusion that the Bair Hugger is capable of causing deep joint infections in orthopedic patients.

For all these reasons, along with the arguments presented in Plaintiffsô related submissions, the Court should deny 3Môs motion for summary judgment.

V. MINNESOTA LAW

A. Summary Judgment Standard

Under Minnesota law, ñ[a] motion for summary judgment may be granted when the pleadings, depositions, answers to interrogatories, admissions and affidavits show that there is no genuine issue as to any material fact and that either party is entitled to judgment as a matter of law.ò *Grondahl v. Bulluck*, 318 N.W.2d 240, 242 (Minn. 1982); *see also* Minn. R. Civ. P. 56.03. When reviewing and ruling on a motion for summary judgment, ñ[t]he district court must view the evidence in the light most favorable to the

[141] *See* Ex. 40 (339:19ï 23); *id.* (304:9-346:13)(explaining that experiment was improperly conducted, performed, and analyzed, so it would not have been worthy of publication).
[142] *See* Ex. 46 (55:20-56:3).

nonmoving party.ò *Id.* ñSummary judgment is a blunt instrument and should be employed only where it is perfectly clear that no issue of fact is involved.ò *Nord v. Herreid*, 305 N.W.2d 337, 339 (Minn. 1981) (internal quotation omitted).

Here, Defendants have moved for summary judgment based on their omnibus motion to entirely exclude Plaintiffsô medical experts. Because Plaintiffs have offered qualified experts to provide reliable, relevant testimony and opinions, Defendantsô motion for summary judgment should be denied.

B. ***Frye-Mack*** **Does Not Bar Plaintiffs' Experts' Testimony Because Plaintiffs' Experts' Methodologies Are Neither New Nor Novel**

The *Frye-Mack* standard regarding the admissibility of expert opinion only applies to expert testimony and opinions which are based on a new or novel scientific theory. *See Jacobson v. $55,900 in U.S. Currency*, 728 N.W.2d 510 (Minn. 2007) (stating *Frye-Mack* analysis not necessary since at-issue testimony was not a new or novel scientific principle); *see also State v. Jensen*, 482 N.W.2d 238, 239 (Minn. Ct. App. 1992) (holding *Frye-Mack* did not apply because the principles at issue were not emerging or novel). According to the advisory comment to Minnesota Rule of Evidence 702, the *Frye-Mack* Rule ñdoes not define what is novel, leaving this for resolution by the courts.ò Minn. R. Evid. 702 (citing *State v. Klawitter*, 518 N.W.2d 577, 578-86 (Minn. 1994) and *State v. Hodgson*, 512 N.W.2d 95, 98 (Minn. 1994)).

The Defendant seeks to exclude the expert opinions of Plaintiffsô experts, who, brick-by-brick, offer their opinions establishing that Bair Hugger causes an increase in bacteria-laden particles to travel through the turbulent, unidirectional air in an operating

room to the patientôs surgical site, resulting in deep join infections. More specifically, the Defendants seek to ódivide and piecemealô Plaintiffsô expertsô opinions on causation by arguing that no one expert offers expert testimony on the ultimate issue: whether the Bair Hugger causes bacteria-laden particles to travel to the surgical site to cause a deep joint injection. The fact that bacteria cause infections is uncontroverted. The fact that bacteria travel on particles is well established. Defendants admit all studies show an increase in the number of particles over the surgical site when the Bair Hugger is turned to ñwarmò.

The fact that Plaintiffsô expertsô combined opinions ï connecting the dots from Bair Hugger to particles to bacterial load to disruption of the airflow in an operating room to deep joint infections - is what Defendantsô motion alleges is new and novel, not generally accepted, and scientifically unreliable. The same could not be further from the truth. First, it is important to note that all of the experts agree that bacteria that cause deep joint infections traveled to the surgical site during the operation; the bacteria did not tunnel in from a nearby organ or hitch a ride through the patientôs arterial system. However, even standing alone, it is clear that Bair Huggers can and do cause bacteria-laden particles to travel to the surgical site to cause infection and resulting injury. The methods by which Plaintiffsô experts arrive at their respective opinions is well within each expertôs respective wheelhouse. None employ new or novel methodologies. Accordingly, *Frye-Mack* cannot be weaponized to bar such testimony.

In *Gelsthorpe v. Weinstein*, 897 So. 2d 504, 507ï 08 (Fla. Dist. Ct. App. 2005), the court considered whether to exclude an opinion based on differential diagnosis, and concluded that it is error to treat ña typical opinion on medical causation as a new

principle, subject to *Frye* analysis, simply because some other experts disagree with it and because the challenged expert does not rely on any specific authority to support his particular opinion.ò *Id* at 511. Of course, in this case, Plaintiffsô experts have supplied significant medical literature and authority in support of their causation opinions. Accordingly, Plaintiffsô expertsô testimony is not subject to the *Frye-Mack* analysis at all. Because Plaintiffsô experts offer reliable, relevant opinion testimony, the Defendantsô motions should be denied.

Plaintiffs hereby incorporate and reference all facts and legal argument made in their memorandums opposing Defendantsô *Daubert* motions as well. Defendants misstate the law applicable in Minnesota state courts regarding admissibility of expert testimony. Because the methodology utilized by each of Plaintiffsô experts is neither new nor novel, *Frye-Mack* does not apply; expert testimony that is relevant and reliable should be admitted.

C. In The Alternative, Even Assuming Arguendo That Plaintiffs' Experts' Opinions on Causation Is Determined to be New Or Novel, The Methods by Which Plaintiffs' Experts Reach Their Respective Opinions are Generally Accepted In The Relevant Community And Scientifically Reliable And Thus Admissible

Alternatively, even if this Court were to apply the *Frye-Mack* standard to Plaintiffsô experts, each has demonstrated appropriate qualifications, proper methodology, and reliable testing to satisfy *Frye-Mack*. Although a *Frye-Mack* analysis is not warranted to Plaintiffsô evidence and the opinions regarding the fact of aerosolization of bacteria-laden particles and how this aerosolization causes deep joint infections, each of the respective expertôs opinions surely pass *Frye-Mack* analysis. ñThe

Frye-Mack standard asks first whether experts in the field widely share the view that the results of scientific testing are scientifically reliable, and second whether the laboratory conducting the tests in the individual case complied with appropriate standards and controls.ò *State v. Roman Nose*, 649 N.W.2d 815, 819 (Minn. 2002). ñUnder the *Frye* prong of the *Frye-Mack* standard, the trial judge defers to the scientific community's assessment of a given **technique**.ò *State v. Taylor*, 656 N.W.2d 885, 891 (Minn. 2003)(emphasis added). ñThe decisions of other appellate courts may be relevant evidence at an evidentiary hearing on the general acceptance of a scientific technique within the relevant scientific community.ò *Roman Nose*, 649 N.W.2d at 820. As the Minnesota Supreme Court has made abundantly clear, ñthe test, then, requires neither unanimity nor acceptance outside its particular field.ò *State v. Fenney*, 448 N.W.2d 54, 58 (Minn. 1989).

In other words, simply because there is a disagreement among experts does not mean a theory is not generally accepted. Results oriented analysis as to reliability of testing is inappropriate; rather, the appropriate question is two-fold: (1) is the testing method generally accepted, and (2) was the test conducted correctly. What any given practitioner may understand or interpret the test results to mean is an entirely irrelevant question at the admissibility stage. The fact that one or more defense experts may disagree with some of the opinions of the Plaintiffsô experts offer does not mean the *theory* (i.e. Bradford-Hill, differential diagnosis, CFD, etc.) is not accepted, it only means there is a triable issue of fact for the jury to resolve.

The opinions cited herein on how and why bacteria-laden particles travel to the surgical site during an operation when the Bair Hugger is set to warm, and the methodology utilized in reaching those opinions are generally accepted in the relevant medical, engineering, and other expert communities and therefore satisfies the first prong of the *Frye-Mack* standard.

The Minnesota Courts have not set a bright-line test for determining whether a specific methodology or opinion is ñscientifically reliable.ò Again, it is critical to note that the methodology used to render the opinions held by the various experts offered by Plaintiffs in this case are nothing new to science; in fact it is the bedrock of science, including basic principles of physics and engineering, evidence based medicine, differential diagnosis, and computational fluid dynamics. Here, the experts have reviewed the applicable materials including medical records, laboratory studies, depositions, and internal company documents. The experts reviewed the underlying medical and scientific data. The experts relied upon their training, education, and experience including reference to applicable literature. The experts each rendered opinions, held to a reasonable degree of professional certainty, as to the applicable ñbrickò in the wall that establishes general causation in this case: what causes bacteria to become aerosolized, and the impact that bacteria can have when it is transported to a patientôs surgical site. Each opinion offered by Plaintiffsô experts is grounded in sound, time-honored science.

In *Goeb*, the court found the plaintiffôs methodology was unreliable ï largely based upon the fact that the expert got the bulk of the data upon which they relied from the attorney. *See Goeb v. Tharaldson*, 615 N.W.2d 800, 815 (Minn. 2000) (affirming that

the challenged methodologies failed the second prong of the Frye-Mack standard). In so finding, the Minnesota Supreme Court looked at several factors including: the source of the expertôs data that formed the basis of his opinion, the failure of the expert to explain countervailing opinions, whether the methodology was peer-reviewed, whether the methodology is used by other experts in the field. *Goeb*, 615 N.W. 2d. at 815. *See also Fenney,* 448 N.W.2d at 57-58 (ñ[t]he scientific *technique* on which expert testimony is based must be scientifically reliable and broadly accepted *in its field*,ôò [. . .] ñ[t]he test, then requires neither unanimity nor acceptance outside its particular fieldò)(quoting *State v. Anderson*, 379 N.W.2d 70, 79 (Minn. 1985) (emphasis added).

In this case, each expert based their opinion, not on information from counsel, but from each expertôs independent review of all the underlying relevant data available in this case ï including the medical records, laboratory studies, computational fluid dynamics models, etc. Applicable medical literature was considered. Then based on the experts training, education, and experience, causation opinions were rendered.

Moreover, while it is not necessary to re-summarize the entire body of literature cited by each of Plaintiffsô experts, it is obvious that there is ample peer-reviewed support for their opinions. These are not methodologies and/or opinions espoused by a single individual that is used only in the courtroom. To the contrary, and in direct contrast to Defendantsô assertions, Samet, Jarvis, Stonnington, and Elghobashi employed the same level of rigor in reaching the opinions offered in their respective expert reports that they each employ in their professional, academic work.

Therefore, the methodology of particle sampling, computational fluid dynamics modeling, evidence-based medicine, and the use of differential diagnosis is scientifically reliable. Plaintiffsô expertsô theories on causation, challenged by the defense, each pass the second prong of the *Frye-Mack* standard. Thus, the opinions of all of the Plaintiffsô experts regarding the role of Bair Hugger in causing aerosolization of bacteria-laden particles, and the mechanism by which the Bair Hugger transports these bacteria-laden particles to a patientôs surgical site causing deep joint infection, are admissible in their entirety and create a genuine issue of material fact, necessitating the denial of the DefendantsôMotion for Summary Judgment.

VI. CONCLUSION

Because Plaintiffs have offered qualified, reliable, relevant expert testimony, opinion, and evidence showing Bair Hugger is capable of causing PJI, Defendants cannot meet their burden of demonstrating no genuine issue of material fact. Accordingly, Defendantsô request for summary judgment, which is predicated solely on an attempt to completely exclude the three medical experts offered by Plaintiffs, Plaintiffs respectfully submit that summary judgment must be denied.

Respectfully submitted,

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